SENATE BILL No. 472

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-7-2-132.5; IC 12-15-35.

Synopsis: Prior authorization for prescription drugs under the Medicaid program. Imposes certain conditions before prior approval may be required for a narrow therapeutic index drug under the Medicaid program. Authorizes the drug utilization review board to implement a uniform Medicaid managed care formulary. Requires a process that allows for a medically necessary prescription to be filled in an emergency. Requires the office of Medicaid policy and planning to implement the board's uniform Medicaid managed care formulary.

Effective: July 1, 2002.

Simpson

January 14, 2002, read first time and referred to Committee on Health and Provider Services.

Introduced

Second Regular Session 112th General Assembly (2002)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2001 General Assembly.

SENATE BILL No. 472

A BILL FOR AN ACT to amend the Indiana Code concerning human services.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-7-2-132.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 132.5. "Narrow therapeutic index drug", for purposes of IC 12-15-35, has the meaning set forth in IC 12-15-35-9.5.**

SECTION 2. IC 12-15-35-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 9. As used in this chapter, "intervention" means an action taken by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices or utilization of drugs, **including the requirement of authorization before dispensing a drug.**

SECTION 3. IC 12-15-35-9.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 9.5. "Narrow therapeutic index drug" means a drug:**

(1) that has less than a two-fold difference in median lethal dose (LD50) and median effective dose (ED50) values; or

(2) that:

(A) has less than a two-fold difference in the minimum toxic concentrations and minimum effective concentrations in the blood; and

(B) for safe and effective use, requires careful titration and patient monitoring.

SECTION 4. IC 12-15-35-31 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 31. (a) An intervention developed under ~~section 28(4) of~~ this chapter that involves a physician must be approved by at least three (3) of the four (4) physician members of the board before implementation.

(b) An intervention that involves a pharmacist must be approved by at least three (3) of the four (4) pharmacist members of the board before implementation.

(c) Interventions include the following:

(1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the board's duties and powers.

(2) Written, oral, or electronic reminders of recipient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care.

(3) Use of face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention.

(4) Intensified reviews or monitoring of selected prescribers or pharmacists.

(5) The creation of an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices.

(6) The timely evaluation of interventions to determine if the interventions have improved the quality of care.

(7) The review of case profiles before the conducting of an intervention.

(8) The imposition of any restriction, including requiring authorization before dispensing a drug.

(9) The implementation of a disease management program.

SECTION 5. IC 12-15-35-34 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 34. (a) Information that identifies an individual collected under this chapter is confidential and

may not be disclosed by the board **or by the board's contractor.**

(b) The board may have access to identifying information for purposes of carrying out intervention activities. The identifying information may not be released to anyone other than a member of the board **or the board's contractor.**

(c) The board may release cumulative non-identifying information for purposes of legitimate research.

SECTION 6. IC 12-15-35-35, AS AMENDED BY P.L.231-1999, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) Before the board develops a program to place a single source drug **or a narrow therapeutic index drug** on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) **Attempt to implement a less restrictive method of intervention, through:**

(A) provider notification;

(B) provider education; or

(C) a disease management program;

that failed.

(2) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

~~(2)~~ **(3)** Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board

meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after the notification.

~~(3).~~ **(4)** Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

~~(4)~~ **(5)** Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

~~(5)~~ **(6)** Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

~~(6)~~ **(7)** Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(8) Ensure that any prior approval program or restriction on the use of a single source drug is not applied unless a less invasive method, including:

(A) provider notification;

(B) provider education; or

(C) a disease management program;

was attempted, but failed.

(c) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(d) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing ~~its recommendations to the office.~~ **the board's programs for the use of multisource drugs.**

SECTION 7. IC 12-15-35-46, AS ADDED BY P.L.231-1999, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE

JULY 1, 2002]: Sec. 46. (a) This section applies to a managed care organization that enters into ~~an initial~~ **a** contract with the office to be a Medicaid managed care organization. ~~after May 13, 1999.~~

~~(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.~~

~~(c) The office shall forward the formulary to the board for the board's review and recommendation.~~

(b) The board shall implement a uniform formulary for all Medicaid managed care organizations that contract with the office.

~~(d)~~ **(c)** The office shall provide at least thirty (30) days notification to the public that the board will review ~~a~~ **the** Medicaid managed care ~~organization's proposed~~ formulary at a particular board meeting. The notification shall contain the following information:

(1) A statement of the date, time, and place at which the board meeting will be convened.

(2) A general description of the subject matter of the board meeting.

(3) An explanation of how a copy of the formulary to be discussed may be obtained.

The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.

~~(e)~~ **(d)** In reviewing the formulary, the board shall do the following:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the ~~use of~~ **inclusion or exclusion of a specific single source drug within a therapeutic class in** the formulary will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Make a determination that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary;

(B) a process is in place through which a Medicaid member has access to **drugs considered** medically necessary ~~drugs;~~ **by a physician within twenty-four (24) hours or immediately in an emergency;** and

(C) the managed care organization otherwise meets the requirements of IC 27-13-38.

~~(f)~~ **(e)** The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing ~~its recommendation to the office.~~ **the managed care formulary under subsection (b).**

~~(g)~~ **(f)** Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.

~~(h)~~ **(g)** The office shall ~~rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.~~ **implement the board's managed care formulary.**

~~(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.~~

~~(j)~~ **(h)** The managed care organization must comply with the ~~office's~~ **managed care formulary** decision within sixty (60) days after receiving notice of the ~~office's~~ **board's** decision.

~~(k) Notwithstanding the other provisions of this section, the office may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.~~

SECTION 8. IC 12-15-35-47, AS ADDED BY P.L.231-1999, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 47. ~~(a) This section applies to the following changes to a formulary used by a Medicaid managed care organization for Medicaid recipients:~~

~~(1) Removing one (1) or more drugs from the formulary.~~

~~(2) Placing new restrictions on one (1) or more drugs on the formulary.~~

~~(b) Before a Medicaid managed care organization makes a change described in subsection (a), the managed care organization shall submit the proposed change to the office.~~

~~(c) The office shall forward the proposed change to the board for the board's review and recommendation.~~

~~(d) The office shall provide at least thirty (30) days notification to the public that the board will:~~

~~(1) review the proposed change; and~~

~~(2) consider evidence and credible information provided to the board;~~

~~at the board's regular board meeting before making a recommendation to the office regarding whether the proposed change should be approved or disapproved.~~

~~(e) Based on the final recommendation of the board, the office may approve or disapprove the proposed change. If a proposed change is not disapproved within ninety (90) days after the date the managed care organization submits the proposed change to the office, the managed care organization may implement the change to the formulary.~~

~~(f)~~ A Medicaid managed care organization:

(1) may add a drug to the managed care organization's formulary without the approval of the office; and

(2) shall notify the office of any addition to the managed care organization's formulary within thirty (30) days after making the addition.